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EXAMINER

WARE, DEBORAH K

ART UNIT PAPER NUMBER

1651

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/015,939	Applicant(s) KADKADE, PRAKASH	
	Examiner Deborah K. Ware	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,22,23,25 and 61-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,22,23,25 and 61-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05272004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-8, 22-23, 25, 61-75 are presented for reconsideration on the merits.

Amendment Papers

The amendments of April 16, 2004, and extension of time are acknowledged. These amendments overcome the double patenting and 35 USC 112, second paragraph issues set forth in the action of December 16, 2003.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 27, 2004, was filed after the mailing date of the action on December 16, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Election/Restrictions

The arguments filed October 13, 2004, have been deemed persuasive in overcoming the restriction requirement of July 13, 2004, hence the restriction has been removed and all claims will be rejoined and examined on the merits.

Claim Objections

Claim 3 is objected to because of the following informalities: the “;” at line 3 after “Tsuga” should be changed to a --,-- . Appropriate correction is required.

Substantial Duplicate

Claim 64 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 8. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight

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difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 23, 25, and 71--75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 75, 23, 25 and 71-74 are rendered vague and indefinite for the recitation of "a medium having at least one ethylene inhibitor, oxygen radical scavenger, divalent cation, a second cryoprotective agent that is the same or different from the first cryoprotective agent, or combinations thereof" wherein it is unclear whether these ingredients are all required by the medium or not? The metes and bounds of the claims can not be determined.

Also claim 74 recites the limitation "the cryoprotective agent" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is unclear whether "the first cryoprotective agent" or "the second cryoprotective agent" is intended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 22 and 61-70 rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Panis et al in view of newly cited Fretz et al, newly cited EP 0 147 236 and newly cited Cino et al.

Claims are drawn to a method for recovering plant cells from cryopreservation comprising obtaining cryopreserved plant cells, thawing the cells, incubating the cells in a medium comprising at least one cryoprotectant agent and a stabilizer and removing the agent and recovering the thawed plant cells. The plant cells can be of the genus species *Taxus brevifolia* or *Musca* or *Picea* or *Daucus* or *Catharanthus*. Also a regrowth step can be carried out by the process. The agent can be glycerol or DMSO in a concentration of about 0.5 M to 2 M and present in a concentration of from about 5% to about 20% by weight. Thawing takes place at a rate of at least about 30 degrees Celsius to about 60 degrees Celsius per minute or can be at about 140 degrees Celsius per minute.

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Panis et al teach obtaining cryopreserved plant cells, thawing the cells, and recovering the thawed plant cells, see page 337, all lines and entire document. The plant cells can be of the genus *Musca* or *Picea* or *Daucus* or *Catharanthus*, see pages 339, line 6, page 343, line 3, page 345, line 21, and page 348, lines 1-20. Also a regrowth step can be carried out by the process, see page 337, line 24. The agent can be a carbon source such as glycerol or it can be DMSO, wherein the agent is in a concentration of about 0.5 M to 2 M and present in a concentration of from about 5% to about 20% by weight, see page 340, lines 35-50. Thawing takes place at a rate of at least about 30 degrees Celsius to about 60 degrees Celsius per minute, see page 340, line 7. MS-salts are used for recovery also, page 340, line 22. Removal of the agent by washing is disclosed at page 340, lines 7-8. Thawing can occur above 40 degrees Celsius, see page 337, line 20.

Panis et al does not disclose incubation technique in a medium containing cryoprotectant and stabilizer or use of *Taxus brevifolia* plant cells.

Fretz et al teach incubation after thawing for regeneration of plant cells, see page 141, lines 1-21.

EP Patent 0 147 236 teaches regeneration of plant cells in a medium containing a stabilizer, such as silver nitrate and other well known inhibitors, and carbon sources such as sugars, note pages 6-7, all lines.

Cino et al teach a medium and culture therefore, of *Taxus brevifolia* cells, see column 2, lines 46-47.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a method for the recovery of cryopreserved plant cells as disclosed by Panis et al, using the incubation technique of Fretz et al on a regeneration medium containing a stabilizer as disclosed by the EP Patent and further to select for *Taxus* plant cells as disclosed by Cino et al. The presence of cryoprotectants as disclosed by Panis et al in the medium of the EP Patent would have been expected to work because these agents can be selected from sugars and the medium of the EP Patent clearly teaches the presence of sugars to provide for a successful combination of ingredients for the recovery of plant cells. It should be noted that sugars are encompassed by cryoprotectants.

One of skill in the art would have expected successful results with the combination of stabilizer and cryoprotectant in a medium because these two ingredients are disclosed by the cited prior art combination to be useful for recovering plant cells. The process steps are disclosed by Panis et al and Fretz et al: obtaining cryopreserved plant cells, thawing, incubating, and removal of cryoprotectant and recovering thawed plant cells. The cells are not disclosed by the art to have been genetically or phenotypically altered in any way.

Further, the thawed cells are incubated in a liquid as disclosed by Fretz et al, see page 142, all lines. In addition, the cells can be pretreated. Further to select for a heating temperature of about 140 degrees Celsius is well within the skill of an artisan who is capable of ascertaining such optimal conditions. Also Panis et al clearly teach thawing temperatures of 40 degrees Celsius and above,

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see page 337, all lines. Successful results would have been expected based upon the reading of the combination of cited prior art. In the absence of convincing and persuasive evidence to the contrary the claims are deemed prima facie obvious.

Claims 23, 25 and 71-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Panis et al in view of newly cited Fretz et al, newly cited EP 0 147 236.

In addition to the descriptions discussed above, the claims are additionally drawn to a medium having a divalent cation such as calcium, magnesium or manganese, and ethylene inhibitor such as silver salt or some other well known one can be used for recovering the plant cells. Further, a sucrose agent can be applied as a cryoprotectant agent.

Panis et al teach obtaining cryopreserved plant cells, thawing the cells, and recovering the thawed plant cells, see page 337, all lines and entire document. The plant cells can be of the genus *Musca* or *Picea* or *Daucus* or *Catharanthus*, see pages 339, line 6, page 343, line 3, page 345, line 21, and page 348, lines 1-20. Also a regrowth step can be carried out by the process, see page 337, line 24. The agent can be a carbon source such as glycerol or it can be DMSO, wherein the agent is in a concentration of about 0.5 M to 2 M and present in a concentration of from about 5% to about 20% by weight, see page 340, lines 35-50. Thawing takes place at a rate of at least about 30 degrees Celsius to about 60 degrees Celsius per minute, see page 340, line 7. MS-salts are used for recovery also, page 340, line 22. Removal of the agent by washing

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is disclosed at page 340, lines 7-8. Thawing can occur above 40 degrees Celsius, see page 337, line 20. Sucrose is disclosed at page 340, last line. Further, DMSO is taught to play a role as a free radical scavenger, note page 345, lines 19-20.

Panis et al does not disclose incubation in a medium having at least one ethylene inhibitor and/or divalent cation.

Fretz et al teach incubation after thawing for regeneration of plant cells, see page 141, lines 1-21.

EP Patent 0 147 236 teaches regeneration of plant cells in a medium containing a silver salt, such as silver nitrate and other well known inhibitors, and carbon sources such as sugars, note pages 6-7, all lines. Further, divalent cations are disclosed, see page 6, lines 28, 29 and page 7, line 6.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for a method of recovering cryopreserved plant cells as disclosed by Panis et al using different cryoprotective agents and an additional step of incubation of thawed plant cells with the agents in a medium containing at least one silver salt, such as silver nitrate and other well known inhibitors in the art, and divalent cations as disclosed by Fretz et al and EP Patent 0 147 236. Clearly one of skill in the art would have been motivated to combine these well known ingredients in the art for the purpose of recovering plant cells. There is no unexpected successful result obtained by the claimed process of which each step of said process is disclosed by the cited prior art combination. Therefore, in the absence of

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convincing and persuasive evidence to the contrary the claims are rendered prima facie obvious over the cited prior art.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449.

Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware
January 8, 2005